OCT 1 2 2001

K012425

Ocular Sciences *(ocufilcon D) soft (hydrophilic) contact lens*	*510(K) PREMARKET NOTIFICATION* **SUMMARY OF SAFETY AND SUBSTANTIAL EQUIVALENCE**	Reference : OCDM55 Section : 3 Version : 3 Page : 1 / 4

0. APPLICANT'S NAME AND ADDRESS

Ocular Sciences Inc.
1855 Gateway Blvd.
Suite 700
Concord, CA 94520
USA

Contact Person

Richard Lippman, OD FAAO
Senior Consultant
C.L. McIntosh & Associates, Inc.
12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20852
Telephone: (301) 770-9590
Fax: (310) 770-9584

1. IDENTIFICATION OF DEVICE

Common Name:	Hydrophilic Soft Contact Lens
Trade Name:	Biomedics® UV Multifocal (ocufilcon D) Soft(Hydrophilic) contact lens
Classification:	Daily Wear Soft (hydrophilic) Contact Lens
Device classification:	Class II (21 CFR 886.5925 (b) (1))

2. DESCRIPTION OF DEVICE

The BIOMEDICS® UV Multifocal (ocufilcon D) Soft (Hydrophilic) Contact Lenses are available with in monomer tint
(Vat Blue 9) and with ultraviolet absorbing additive (benzophenone based):

- in the power range of –20.00 to +10.00 diopters for sphere,
  +0.25 to +3.00 diopters for addition
- with center thickness from 0.025mm to.40mm
- with base curves of 8.00mm to 9.20mm
- with diameter of 12.00mm to 15.00mm

The lens material is the same as the one BIOMEDICS® UV (ocufilcon D) described in submission PMA890023/S4 and S7 ,K984046.
The Biomedics® UV Multifocal (ocufilcon D) Soft (Hydrophilic) Contact Lens has a spherical posterior surface. The anterior (convex) surface is constructed in lenticular form to provide optimum edge thickness and contour. This optical surface allows for correction of visual acuity in non-aphakic persons with non-diseased eyes that are presbyopic, with or without associated ametropia, allowing for the correction of up to +3.00 diopters of add, with refractive astigmatism of no more than 0.75 diopters that does not interfere with visual acuity. The multifocal lens is a aspheric center near design.

3. INTENDED USE

The BIOMEDICS® UV Multifocal (ocufilcon D) Soft (Hydrophilic) Contact Lenses are indicated for daily wear The eye care practitioner may prescribe the contact lens for either single use disposable wear and for frequent replacement wear. When prescribed for frequent replacement/planned replacement the lens may be disinfected using a chemical or hydrogen peroxide disinfecting systems.

The BIOMEDICS® UV Multifocal (ocufilcon D) Soft (Hydrophilic) Contact Lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are presbyopic, with or without

associated ametropia. The lens may be worn by persons who require up to +3.00 diopters of addition and who exhibit refractive astigmatism of 0.75 diopters or less that does not interfere with visual acuity.

The BIOMEDICS® UV Multifocal (ocufilcon D) Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

4. PREDICATE DEVICES

The predicate lenses were selected to address: material (FDA Group IV: high water, ionic polymer), intended use (daily wear) and lens designs (sphere, multifocal).

Lens material, spherical lens design and intended use:
BIOMEDICS® UV (ocufilcon D) Sphere Hydrophilic Contact Lenses, FDA Group IV, high water content, ionic soft contact lenses for daily wear marketed internationally by OCULAR SCIENCES Inc. under PMA 890023/S7 and K984046.

Multifocal lens design:
Rythmic® UV (surfilcon A) Hydrophilic Contact Lenses, FDA Group II, high water content, non ionic soft contact lenses for daily wear marketed internationally by OCULAR SCIENCES Inc under K003170

5. CHARACTERISTICS

The characteristics of the Biomedics® UV Multifocal (ocufilcon D) Soft(Hydrophilic) contact lens are compared to the characteristics of the predicate device Biomedics® UV sphere in the following table.

TABLE 1

Material comparison		
	Predicate device **BIOMEDICS® UV Sphere**	Subject device **BIOMEDICS® UV Multifocal**
PRODUCTION METHOD	Cast molded process	Cast molded process
INTENDED USE	Extended and daily wear Correction of ametropia	Daily wear Correction of ametropia and presbyopia
MATERIAL	ocufilcon D	ocufilcon D
Type	Group IV	Group IV
Color additive	Vat Blue 6 Dye CFR 130-20-1	Vat Blue 6 Dye CFR 130-20-1
UV additive	Yes	Yes
Characteristics comparison	*Labeled*	*Labeled*
Water Content % @ 20°C	55	55
Refractive Index @ 20°C	1.41	1.41
Dk, Polarimetric method with edge correction @ 35°C x 10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg)	19.6	19.6
Elongation at break, % @ 20°C	NA	NA
Mechanical strength, Mpa @ 20°C	NA	NA
Light transmittance	Tv, % @ 20°C Illuminant A with a 2° observer (between 380 and 780 nm) 97%	Tv, % @ 20°C Illuminant A with a 2° observer (between 380 and 780 nm) 97%

TABLE 2

Lenses design comparison		
	Predicate spherical device **BIOMEDICS® UV Sphere**	Subject spherical device **BIOMEDICS® UV Multifocal**
Characteristics comparison, -3.00 D 30 lenses	*Labeled*	*Labeled*
Base Curve, mm	8.60	8.60
Diameter, mm	14.20	14.20
Power, D	-3.00	-3.00
	Predicate multifocal device **RYTHMIC® UV Multifocal**	Subject multifocal device **BIOMEDICS® UV Multifocal**
Characteristics comparison, -3.00 D 30 lenses	*Labeled*	*Labeled*
Power, D	-3.00	-3.00

6. NON CLINICAL STUDIES

Non-clinical studies provided by reference PMA890023 S4/S7 and K984046

- Chemistry
- Cast molded manufacturing process
- Toxicology data: lens and packaging materials
- Residual (leachables) Monomer
- Shelf life data
- Microbiology and sterilization
- Packaging

7. CLINICAL DATA

It was determined that Clinical Studies were not necessary to establish the safety and efficacy of the Biomedics® UV Multifocal lenses. This determination was based on the following:

- The Biomedics® UV Multifocal (ocufilcon D) Soft(Hydrophilic) contact lens were proven to be substantial equivalent to the predicate Biomedics® UV Sphere lenses(PMA890023/S4 and S7 and K984046). Showed substantial equivalence in physiochemical characteristics and parameters.
- The Biomedics® UV Multifocal (ocufilcon D) Soft(Hydrophilic) contact lens design was proven to be equivalent to the predicate multifocal lenses: Rythmic® UV Multifocal lenses from Ocular Sciences(K003170).

8. CONCLUSIONS DRAWN FROM STUDIES

Substantial Equivalence:

The information provided in this 510K establishes that the Biomedical® UV Multifocal (ocufilcon D) soft (Hydrophilic) contact lenses are equivalent in optical, chemical and physical properties of the predicate devices and do not raise any questions of safety and effectiveness. There for the device is substantially equivalent to the predicate device.

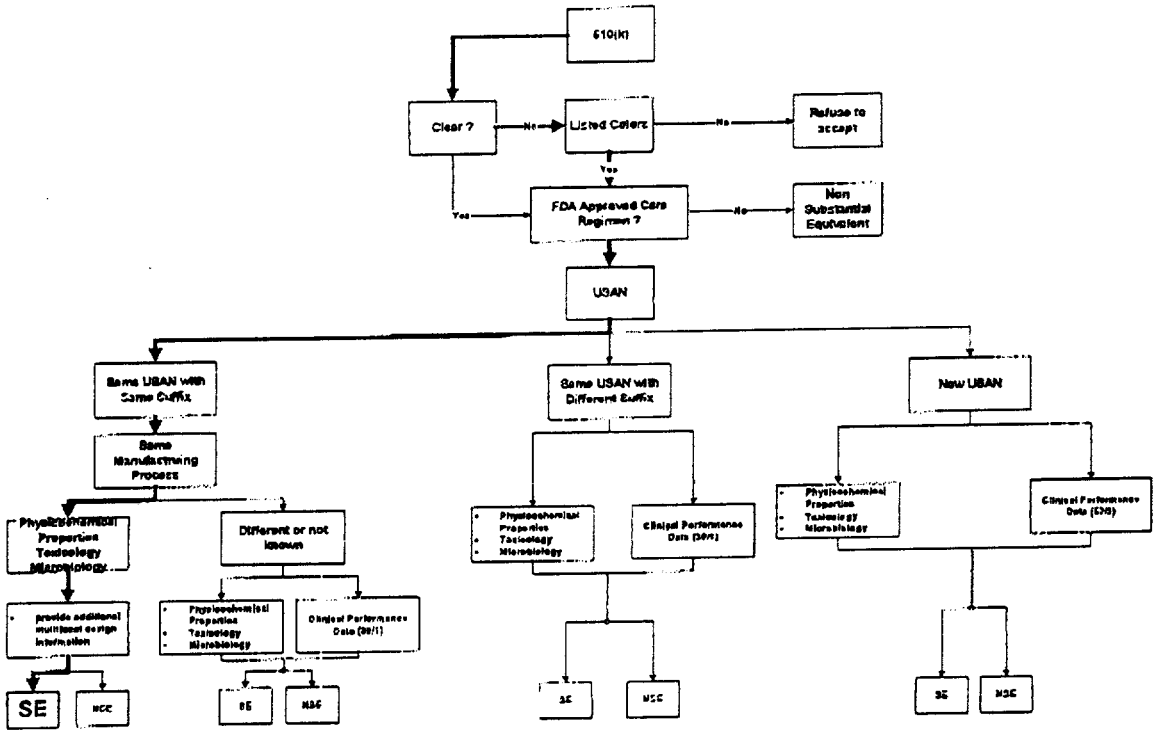
Risk and Benefits:

The risks of the subject device are the same as those normally attributed to the wearing of soft (hydrophilic) contact lenses on a daily wear base. The benefits to the patient are the same as those for other soft (hydrophilic) contact lenses.

9. Route chosen in the Flow Chart for 510 (K) Daily Wear Contact Lens

FIGURE 1

Biomedics® UV Multifocal



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 2 2001

Ocular Sciences, Inc.
c/o Richard E. Lippman, O.D., F.A.A.O.
CL McIntosh & Associates, Inc.
12300 Twinbrook Parkway
Suite 625
Rockville, MD 20852

Re: K012425
Trade/Device Name: Biomedics® UV Multifocal (ocufilcon D) Soft (hydrophilic) Contact Lens for Daily Wear (visibility tint, cast molded)
Regulation Number: 21 CFR 886.5925 (b) (1)
Regulation Name: Soft (hydrophilic) Contact Lens for Daily Wear
Regulatory Class: Class II
Product Code: LPL
Dated: July 24, 2001
Received: July 30, 2001

Dear Mr. Lippman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATION FOR USE STATEMENT

510(k) Number (if known) K012425

Device Name: BIOMEDICS® UV Multifocal (ocufilcon D) Soft (Hydrophilic) Contact Lens

Indications for Use:

The BIOMEDICS® UV Multifocal (ocufilcon D) Soft (Hydrophilic) Contact Lenses are indicated for daily wear. The eye care practitioner may prescribe the contact lens for either single use disposable wear and or for frequent replacement wear. When prescribed for frequent replacement/planned replacement the lens may be disinfected using a chemical or hydrogen peroxide disinfecting system.

BIOMEDICS® UV Multifocal (ocufilcon D) Soft (Hydrophilic) Contact Lenses are indicated for the correction of visual acuity in not-aphakic persons with non-diseased eyes that are presbyopic, with or without associated ametropia. The lens may be worn by persons who require up to +3.00 diopters of addition and who exhibit refractive astigmatism of 0.75 diopters or less that does not interfere with visual acuity.

The BIOMEDICS® UV Multifocal (ocufilcon D) Soft (Hydrophilic) Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Presription Use ✓ OR Over -The-Counter Use _____

(Optional Format 1-2-96)

Ming-Chuen Shih

(Division Sign-off)
Division of Ophthalmic Devices

510(k) Number K012425